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MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA)
ST. LOUIS, MO 63167

EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/531,113
Filing Date: March 22, 2000
Appellant(s): BYRUM ET AL.

Gautam Prakash
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/25/2007 appealing from the Office action mailed 11/30/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Prior art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

Claims 1, 8-13 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed subject matter is not supported by a specific; substantial or a well established utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use.

The claimed invention is drawn to a substantially purified nucleic acid molecule that encodes a soybean protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 5981 or a substantially purified nucleic acid molecule comprising a sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof. As noted earlier, a well-established utility is defined as a specific, substantial and credible utility which is well known, immediately apparent or implied by the specification's disclosure of the properties of the a material, alone or taken with the knowledge of one skilled in the art. The specification discloses a number of general utilities for the nucleic acid molecule

disclosed herein. For example, the specification discloses that the nucleic acid molecules may be used as molecule tags to isolate genetic regions, isolate genes, map genes and determine gene function (page 15), in marker-assisted breeding programs (page 16), as antibodies (page 16), as primer and probes for the isolation of full length cDNAs or genes (page 28), in mutation detection (page 37), in the identification of polymorphism (page 38), as molecular markers (page 50), genetic mapping studies (page 49), in DNA-protein interaction (page 52) in methods of identifying chromosomes with translocation (page 52), in method of protein-protein interaction (page 60), in microarray based methods (page 54), in site directed mutagenesis (page 56) and in methods of transformation (page 61). None of theses asserted utilities are specific because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid and therefore are not particular to the nucleic acid sequence being claimed. Likewise no direct connection is made between the claimed sequence or any of the numerous utilities claimed. The examples beginning at page 85 do not provide any disclosure which demonstrates the functionality of the claimed nucleic acid sequence or fragments thereof or complement thereof as for example, probes and/or primers to detect a mutation or as marker to determine gene function. Thus, further research is required to determine the specific utility of the claimed nucleic acid sequence.

Further, the claimed nucleic acid and/or the encoded protein are not supported by a substantially utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the

protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by Applicant to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the claimed use of the nucleic acid in the instant specification is neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic molecules. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid or the encoded protein such that another non-asserted utility would be well established for the compounds.

Claim Rejections - 35 USC § 112

Claims 1 and 8-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above,

one skilled in the art would not know how to use the claimed invention based on the lack of utility as discussed above.

(10) Response to Argument

Appellant's arguments drawn to the above rejection have been fully reviewed and considered. However, they are not found persuasive for the reasons that follow. The paragraph numbers used in the response to argument section follow those used in the Brief.

7-A. - Appellants allege that they have provided a specific, substantial and credible utility for a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5981. Appellants allege that they have provided a statistically significant correlation between the nucleic acid sequence of SEQ ID NO: 5981 and a nucleic acid molecule encoding a known protein that has been established by a well-known technique. Appellants allege that they have demonstrated that the claimed invention has patentable utility and thus satisfied the utility requirement of 35 USC 101. Appellants allege that because they have satisfied the utility requirement of 35 USC 101, one skilled in the art would know how to make and use the claimed invention, thus satisfying the requirement of 35 USC 112, first paragraph.

In response, it is noted that the specification at pages 21 and 28-29 discloses that the instant invention encodes a soybean protein or fragment thereof. The specification at pages 24 and 25 discloses that nucleic acid molecules of the instant invention or fragments thereof or complements thereof can be used as markers capable of detecting polymorphism. The specification at pages 38-46 provides a general

definition of what constitutes a polymorphism and general means for detecting or determining the existence of polymorphisms as known in the art. However, no disclosure or any polymorphism is provided that is specific to the nucleic acid molecule (SEQ ID NO: 5981) recited in the claims 1 and 8-13. To the contrary, according to appellant's specification (e.g., page 45, 7-9), "one or more of the 48,629 nucleic acids of the present invention, maybe utilized as markers or probes to detect polymorphisms...". The specification does not explain why any of the these nucleic acid molecules disclosed in the specification, or more specifically a nucleic acid molecule comprising the sequence of SEQ ID NO: 5981 would in fact be useful in detecting a polymorphism or whether the claimed nucleic acid molecule can, in fact, be used to detect any polymorphism, whatsoever. The specification generally teaches using the claimed nucleic acid molecules to identify a polymorphism, but fails to teach that a polymorphism could in fact be detected, or whether a "specific" polymorphism could be detected.

Further, the specification provides no information with regards to the genes represented by the nucleic acid or the encoded protein. Accordingly, detecting the presence or absence of a polymorphism as suggested in the instant specification provides the barest information in regards to genetic heritage or association to a disease or condition or any effect of the encoded protein. There are myriad of polymorphisms that are known to occur in nucleic acid molecules in plants, etc, both of the silent type and those that result in significant phenotypic effects. However, without, evidence characterizing those polymorphisms or information concerning the gene(s)

represented by the claimed nucleic acid molecule(s) which may or may not comprises the polymorphisms or some type of association of the polymorphism with a genetic trait, disease or condition, nothing is gains and no substantial, specific or patentable utility is presented. Further research would be required to determine what said detection of polymorphism indicates and thus substantiates the Examiner's assertion that the claimed invention is not enabled due to lack of information provided in the specification and claims. This need for further research also supports the lack of currently available form of utility.

7-B. - Appellants allege that they have demonstrated the utility of SEQ ID NO: 5981 by conducting a BLASTN analysis. Appellants allege that the specification as filed discloses that a BLASTN analysis is a well-known and conventional technique that can be used to obtain information on nucleic acid sequences. Appellant alleges that the results of a BLASTN analysis OF SEQ ID NO: 5891 show that SEQ ID NO: 5981 has 94 percent identity to a sequence obtained from water-stressed *Glycine max*. Appellants submit that the results of the BLASTN analysis demonstrate that SEQ ID NO: 5981 has utilities specific to it and generally applicable to any sequence. Appellants summarize *In re Fisher* and allege that they have satisfied the utility test set forth in *In re Fisher*, i.e., that the utilities of SEQ ID NO: 5981 are specific, substantial and well-established, and provide a well-defined and particular benefit to the public. Appellants alleges that the utility of SEQ ID NO: 5981 is specific because SEQ ID NO: 5981 and not just any general sequence, shares 94 percent identity to a nucleic acid sequence encoding a protein obtained from water stressed *Glycine max*. Appellants allege that the utility is

substantial and credible because SEQ ID NO: 5981 can be used to isolate genes, map genes and determine gene function associated with water stress. Appellant argues that the Office must accept a stated utility by an applicant unless the Office has evidence or sound scientific reasoning to rebut the applicant's assertion. Appellant asserts that "a 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." Appellants cite MPEP 2107.03 and allege that the BLASTN analysis provides such a reasonable correlation through sequence identity. Appellants allege that a 94 percent identity to a sequence obtained from water-stressed *Glycine max* is a reasonable correlation. Appellants allege that they have established at least one specific and substantial utility for the claimed nucleic acid molecules. Appellants allege that the Examiner has mis-characterized Appellants' previous response, and has incorrectly applied the law. Appellants allege that they are not contemplating any further research, nor is any further research required, because the fact that SEQ ID NO: 5981 shares 94% identity to a nucleic acid molecule encoding a protein from water-stressed *Glycine max* provides an immediate and real world benefit to the public.

In response, the Examiner notes that the alleged specific utility based on a BLASTN search of SEQ ID NO: 5981 is not substantial or credible because the Appellants did not contemplate the utility of the claimed nucleic acid molecule at the time the application was filed. The specification provides no evidence or support anywhere to establish that the sequence of SEQ ID NO: 5981 shares 94 percent identity to any nucleic acid molecule, especially, a protein from water-stressed *Glycine max.* In fact, the specification does not recite, disclose or even suggest any association of, or

function of any nucleic acid molecule being involved in water-stressed. Thus, a specific, asserted or credible utility was not readily recognized by Appellants at the time the instant application was filed and only became apparent after performing a BLASTN search, which supports the need for further research and analysis. Utilizing tools such as a BLASTN search, after the application has been filed, may be compared to a "fishing experiment" to see what information can be obtained without knowing what the information means or correspond to. Additionally, in Appellants' remarks submitted on 09/07/2006, Appellants disclose that the nucleic acid molecule encoding a protein from water stressed *Glycine max* was disclosed in an unpublished 2005 study (see page 3). The instant invention however was filed on March 22, 2000. This further substantiates that Appellants were unaware of any specific utility for the instant invention and only speculated general uses thereof for the instant nucleic acid molecule of SEQ ID NO: 5981. Therefore, the Examiner asserts that Applicant's arguments are not persuasive to support a specific, asserted or substantial utility.

7C. - Appellants assert that the rejection under 35 U.S.C. 112, first paragraph has been overcome by the arguments set forth above with respect to the rejection under 35 U.S.C. 101. Appellants allege that the claimed invention has specific, substantial and credible utility, and therefore one skilled in the art would know how to make and use the claimed invention.

In response, it is noted that the enablement rejection is based on the fact that no patentable utility has been set forth for the claimed invention and thus, one would not know how to use the claimed invention based on the disclosure of the specification.

This rejection is simply a corollary of the finding of lack of utility as discussed above. All of the arguments set forth by the Examiner for a lack of utility are applied here for lack of enablement. The Examiner again asserts that since no specific, substantial or well-established utility has been set forth by Appellants, one skilled in the art would not know how to make or use the invention. Accordingly, Appellant's arguments are not persuasive.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Cynthia B. Wilder, Ph.D.
Examiner
Art Unit 1637

cbw
August 22, 2007

Conferees
Ken Horlick
Ram Shukla

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
8/23/07

MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ATTENTION: G.P. WUELLNER, IP PARALEGAL, (E2NA)
ST. LOUIS, MO 63167